

United States Court of Appeals,
 Ninth Circuit.

**Joe KENNEDY, as successor in interest and a
 personal representative of the
 Estate of Ellen Marie Kennedy; Shawn Kennedy;
 Eric Kennedy; Shannon Kennedy, by
 and through her parent and guardian Joe Kennedy;
 and Chad Kennedy, by and
 through his parent and guardian Joe Kennedy,
 Plaintiffs-Appellants,**
 v.
**SOUTHERN CALIFORNIA EDISON COMPANY;
 Combustion Engineering, Inc., Defendants-
 Appellees.**

No. 98-56157.

Argued and Submitted Feb. 10, 2000
 Opinion Filed July 20, 2000
 Opinion Withdrawn Sept. 19, 2001
 Argued on Rehearing and Submitted April 26, 2001
 Filed Sept. 26, 2001

Survivors of spouse of nuclear plant employee, who had died from chronic myelogenous leukemia (CML) that was allegedly caused by her exposure to microscopic radioactive particles inadvertently brought home by employee, brought suit asserting claims against plant operator pursuant to Price-Anderson Act, and also brought products liability claims against manufacturer of nuclear fuel rods used at plant. The United States District Court for the Southern District of California, Napoleon A. Jones, J., dismissed product liability claims, and entered judgment upon jury verdict for defendants. Survivors appealed. The Court of Appeals held that any error in failing to give *Rutherford* instruction that causation could be established under California law by proof that exposure to radioactive material was a substantial factor contributing to risk of developing illness was harmless.

Affirmed.

Opinion, 219 F.3d 988, withdrawn.

[1] Federal Courts ⚡776

170Bk776

Jury instructions challenged as a misstatement of law are reviewed de novo.

[2] Federal Courts ⚡776
 170Bk776

Court of Appeals reviews de novo both a dismissal without leave to amend, and a dismissal with leave to amend.

[3] Electricity ⚡8.5(2)
 145k8.5(2)

[3] Electricity ⚡12.1
 145k12.1

Price-Anderson Act accomplishes its dual purpose of protecting the public, and encouraging the development of the atomic energy industry, by providing certain licensees with a system of private insurance, government indemnification, and limited liability for certain nuclear tort claims. Atomic Energy Act of 1954, as amended, 42 U.S.C.A. § 2011 et seq.

[4] Damages ⚡185(1)
 115k185(1)

In a personal injury action brought under California law, causation must be proven within a reasonable medical probability based upon competent expert testimony.

[5] Damages ⚡185(1)
 115k185(1)

Under California law, in the context of medical injuries with multiple possible causes, a mere possibility that defendant's conduct caused injury, standing alone, is insufficient to establish a prima facie case, and a possible cause only becomes probable when, in the absence of other reasonable causal explanations, it becomes more likely than not that the injury was a result of its action.

[6] Federal Courts ⚡908.1
 170Bk908.1

Harmless error review applies to jury instructions in civil cases; this standard of review is less stringent than review for harmless error in a criminal case, but more stringent than review for sufficiency of the evidence.

[7] Federal Courts ⚡892
 170Bk892

In harmless error review, unlike sufficiency of the evidence review, the prevailing party is not entitled to have disputed factual issues resolved in his favor, because the jury's verdict may have resulted from a misapprehension of law rather than from factual determinations in favor of the prevailing party.

[8] Federal Courts ⚡911
170Bk911

Claimed error in failing to give *Rutherford* instruction that causation could be established by proof that exposure to radioactive material was a substantial factor contributing to risk of developing illness was harmless in action brought under California law against operator of nuclear power plant, and supplier of nuclear fuel rods, by survivors of spouse of employee at plant, whose death from chronic myelogenous leukemia (CML) allegedly resulted from exposure to microscopic radioactive particles brought home by employee, where uncontroverted evidence indicated that, even if spouse was exposed to radioactivity as alleged, there was at best a one in 30,000 chance that it actually caused her illness.

[9] Federal Courts ⚡910
170Bk910

An error in a trial court's jury instructions relating to the parties' respective burdens of proof ordinarily requires reversal.

[10] Evidence ⚡598(1)
157k598(1)

Under a preponderance of the evidence standard, the jury is only required to believe that the existence of a fact is more probable than its nonexistence.

[11] Products Liability ⚡5
313Ak5

Under California products liability law, a manufacturer may be held strictly liable in tort for placing a defective product on the market if that product causes personal injury, provided that the injury resulted from a use of the product that was reasonably foreseeable by the defendants.

[12] Products Liability ⚡8
313Ak8

[12] Products Liability ⚡11
313Ak11

[12] Products Liability ⚡14
313Ak14

Under California law, doctrine of strict products liability extends to products which have design defects, manufacturing defects, or warning defects.

Suzelle M. Smith (argued) and Don Howarth, Howarth & Smith, Los Angeles, California, for the plaintiffs-appellants.

John A. Reding (argued) and Ned N. Isokawa, Paul, Hastings, Janofsky & Walker, San Francisco, California, for the defendants-appellees.

Alfred R. Mollin (argued), U.S. Department of Justice, Washington, D.C., for amicus United States in support of the defendants-appellees.

Robert W. Loewen, Gibson, Dunn & Crutcher, Irvine, California, for amici Lockheed Martin Corporation, The California Chamber of Commerce, The American Chemistry Council, The National Association of Manufacturers, Philips Petroleum and Pfizer, Inc., in support of the defendants-appellees.

Charles F. Rysavy, McCarter & English, Newark, New Jersey, for amici American Public Power Association, Edison Electric Institute, National Rural Electric Cooperative Association, and Nuclear Energy Institute, in support of the defendants-appellees.

Martin S. Kaufman, Atlantic Legal Foundation, New York, New York, for amici Robert K. Adair, Bruce N. Ames, D. Allan Bromley, Patricia A. Buffler, Bernard Cohen, Bernard Gittelman, Sheldon Lee Glashow, Michael Gough, Ronald Hart, Dudley Herschbach, Lawrence Litt, A. Alan Moghissi, Rodney W. Nichols, Robert V. Pound, Norman Ramsey, Joseph P. Ring, Frederick Seitz, Edward Thorndike, Lynn H. Verhey and James D. Watson, in support of the defendants-appellees.

Appeal from the United States District Court for the Southern District of California; Napoleon A. Jones, District Judge, Presiding. D.C. No. CV-95-03769-NAJ/RBB.

Before: Robert Boochever, Michael Daly Hawkins, and Sidney R. Thomas, Circuit Judges.

PER CURIAM:

*1 This appeal requires us to examine California tort

and products liability law as made expressly applicable to actions in federal court for claims of injury arising out of nuclear power plant incidents. Specifically, we must decide whether the district court erred in (1) refusing to give a jury instruction under *Rutherford v. Owens-Illinois, Inc.*, 16 Cal.4th 953, 67 Cal.Rptr.2d 16, 941 P.2d 1203 (Cal.1997), in a case involving a single defendant who raises alternative possible sources of injury as a defense; and (2) dismissing claims under California product liability law. For the reasons set forth below, we affirm the district court's result.

BACKGROUND

Ellen Kennedy died in 1996 of chronic myelogenous leukemia ("CML"). [FN1] She was forty-three years old. The plaintiffs/appellants are her husband, Joe, and their four children (collectively referred to as "Kennedy"). From 1982 to 1990, Mr. Kennedy worked as a machinist for Southern California Edison Company ("Cal Edison") at the company's San Onofre Nuclear Generating Station ("SONGS").

Plaintiffs sued Cal Edison in federal court, asserting jurisdiction pursuant to the Price-Anderson Act, 42 U.S.C. §§ 2011-2297, and seeking damages for Ellen Kennedy's wrongful death, alleging negligence on the part of Cal Edison that resulted in her exposure to radiation from SONGS. Additionally, Kennedy brought a products liability claim against Combustion Engineering, Inc. for the alleged faulty production of nuclear fuel rods. The theory of both claims was that Joe Kennedy inadvertently brought home microscopic particles of radioactive material, known as "fuel fleas," from the power plant on his clothing, hair, tools, etc. These fuel fleas, which according to Kennedy contained dosages in excess of the maximum allowable by federal regulations, allegedly came in contact with Mrs. Kennedy and caused her fatal cancer.

The district court granted Combustion Engineering's motion to dismiss all the products liability claims against it. The court reasoned that, inasmuch as Mrs. Kennedy was not a user or consumer of the nuclear fuel rods Combustion Engineering produced, Combustion Engineering could not have reasonably foreseen that Mrs. Kennedy would be injured by its product.

*2 Kennedy initially sought a burden-shifting order stating that once Kennedy made an initial showing of Mrs. Kennedy's exposure to radiation from SONGS,

Cal Edison and Combustion Engineering would then bear the burden of proving their conduct was not a substantial factor in causing Mrs. Kennedy's death. The district court denied this request.

In August 1997, the California Supreme Court issued its opinion in *Rutherford v. Owens-Illinois, Inc.*, 16 Cal.4th 953, 67 Cal.Rptr.2d 16, 941 P.2d 1203 (Cal.1997), a products liability case brought by the estate of a worker who had been exposed to asbestos-containing products and subsequently died of lung cancer. *Rutherford* dealt in large part with the proper jury instructions on causation to be given when multiple potential causes of harm exist. In light of the decision, Kennedy requested a causation instruction "consistent with *Rutherford*." The district court denied Kennedy's request. Kennedy again requested a *Rutherford* instruction and submitted a proposal twice more before trial. Both requests were again denied.

After a fact-intensive, five-week trial, the jury returned a unanimous verdict in favor of Cal Edison and Combustion Engineering. The district court denied Kennedy's motion for a new trial. The appeal was argued and submitted on February 10, 2000. The initial panel opinion was filed on July 20, 2000. After Cal Edison filed a petition for rehearing, with numerous amici in support, we granted rehearing and held a second round of oral argument. Jurisdiction lies pursuant to 28 U.S.C. § 1291.

STANDARD OF REVIEW

[1][2] Jury instructions challenged as a misstatement of law are reviewed de novo. *City of Long Beach v. Standard Oil Co.*, 46 F.3d 929, 933 (9th Cir.1995). We review de novo both a dismissal without leave to amend and a dismissal with leave to amend. *San Pedro Hotel Co. v. City of Los Angeles*, 159 F.3d 470, 477 (9th Cir.1998); *Sameena, Inc. v. United States Air Force*, 147 F.3d 1148, 1151 (9th Cir.1998).

ANALYSIS

Under the Price-Anderson Act ("Price-Anderson" or "the Act"), our decision is guided by the substantive law of California. Price-Anderson provides federal jurisdiction over lawsuits for injuries arising out of a "nuclear incident." [FN2] Under such "public liability actions," [FN3] the "substantive rules for decision ... shall be derived from the law of the State in which the nuclear incident involved occurs, unless such law is inconsistent with the provisions of [section 2210]." 42 U.S.C. § 2014(hh).

[3] Enacted in 1957 during the fledgling days of the nuclear power industry, Price-Anderson has a dual purpose: "to protect the public and to encourage the development of the atomic energy industry." 42 U.S.C. § 2012(i); *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 64, 98 S.Ct. 2620, 57 L.Ed.2d 595 (1978). The Act accomplishes this by providing certain licensees with a system of private insurance, government indemnification, and limited liability for certain nuclear tort claims. See *El Paso Natural Gas Co. v. Neztosie*, 136 F.3d 610, 616 (9th Cir.1998), *rev'd on other grounds*, 526 U.S. 473, 119 S.Ct. 1430, 143 L.Ed.2d 635 (1999); see also S.Rep. No. 218, 100th Cong., 1st Sess. 2 (1987), reprinted in 1988 U.S.C.C.A.N. 1424, 1476, 1477.

*3 Before its amendment in 1988, Price-Anderson provided the federal courts with original and removal jurisdiction only when the accident at issue was "an extraordinary nuclear occurrence" as defined by the Act at 42 U.S.C. § 2014(j). Responding to a flurry of lawsuits in federal and state courts generated by the 1979 nuclear accident at Three Mile Island, which was not considered "an extraordinary nuclear occurrence," Congress added section 2014(hh) to the Act, thereby providing the federal courts with original and removal jurisdiction for the broader category of "nuclear incidents." *Neztosie*, 526 U.S. at 477.

I. *Rutherford* Instruction

A. Background and Applicability

[4][5] The basic contours of California tort law, in the context of medical injuries with multiple possible causes, are outlined in *Jones v. Ortho Pharm. Corp.*, 163 Cal.App.3d 396, 209 Cal.Rptr. 456 (Ct.App.1985). *Jones* involved cancer alleged to have resulted from a contraceptive pill. The California Court of Appeal stated:

The law is well settled that in a personal injury action causation must be proven within a reasonable medical probability based upon competent expert testimony. Mere possibility alone is insufficient to establish a prima facie case.... A possible cause only becomes "probable" when, in the absence of other reasonable causal explanations, it becomes more likely than not that the injury was a result of its action. This is the outer limit of inference upon which an issue may be submitted to the jury.
Id. at 460.

The Book of Approved Jury Instructions for California ("BAJI") provides two general instructions

on causation for cases involving injuries with multiple potential causes. It was these two instructions—BAJI 3.76 and 3.77—that the district court provided to the jury, neither of which was objected to by any of the parties. BAJI 3.76 provides a definition for "cause:" "The law defines cause in its own particular way. A cause of injury, damage, loss or harm is something that is a substantial factor in bringing about an injury, damage, loss or harm." The other standard jury instruction, BAJI 3.77, pertains to multiple causation. It states:

There may be more than one cause of an injury. When conduct of two or more persons or conduct and a defective product contributes concurrently as causes of an injury, the conduct of each is a cause of the injury regardless of the extent to which each contributes to the injury. A cause is concurrent if it was operative at the moment of injury and acted with another cause to produce the injury.

*4 *Rutherford* addressed the adequacy of these instructions and altered the landscape of California tort law, as it applies to the burden of proof to establish causation for asbestos-induced cancer, when it held that BAJI 3.76 and 3.77 must be augmented by an additional instruction. 67 Cal.Rptr.2d 16, 941 P.2d at 1223. Though the court reiterated traditional California tort principles on causation and cited *Jones*'s "reasonable medical probability" requirement with approval, see *id.* at 1214, 1219 n. 1, it cited four factors in asbestos-related cancer cases that necessitated a departure from the standard jury instructions on causation.

First, the court noted that "there is scientific uncertainty regarding the biological mechanisms by which inhalation of certain microscopic fibers of asbestos leads to lung cancer...." *Id.* at 1218. Second, it discussed the uncertainty that "frequently exists" whether a plaintiff was even exposed to dangerous asbestos fibers produced, distributed or installed by a particular defendant. The court was particularly concerned with the long latency periods of asbestos-related cancers and the many different asbestos-containing products that may have been used at the same time and in the same workplace. See *id.* Third, the court stated that the "question arises whether the risk of cancer created by ... exposure to a particular asbestos-containing product was significant enough to be considered a legal cause of the disease." *Id.* Finally, the court noted the "impossibility" of proving "the unknowable path of a given asbestos fiber." *Id.* at 1219.

Despite these difficulties of proof, the California Supreme Court rejected the argument that the burden of proving causation should shift to the defendants after the plaintiffs had proven exposure. [FN4] The court reasoned that the fundamental justification for a shifting of the burden—that without such a shift *all* defendants might escape liability and the plaintiff be left “remediless”—is absent in asbestos-related cancer cases. *Id.* at 1220 (quoting *Summers v. Tice*, 33 Cal.2d 80, 199 P.2d 1, 4 (Cal.1948)). Moreover, the court pointed out that in asbestos cases, unlike traditional alternative liability cases, the complete set of possible tortfeasors is not before the court, and that given the wide ranging toxicities of different asbestos-containing products, the tortfeasors that are before the court do not display the “same symmetry of comparative fault or indivisible injury” that are the trademarks of alternative liability cases. *Id.* (internal quotations omitted). Having rejected burden-shifting, the California Supreme Court was presented with a Gordian knot of its own making: traditional causation principles presented asbestos-related cancer patients with insuperable barriers to recovery, yet the court had rejected alternative liability as being unsuited for these types of cases.

Rutherford cut the knot by altering, rather than shifting, the plaintiff’s burden. The court held that

*5 plaintiffs may prove causation in asbestos-related cancer cases by demonstrating that the plaintiff’s exposure to defendant’s asbestos-containing product in reasonable medical probability was a substantial factor in contributing to the aggregate dose of asbestos the plaintiff or decedent inhaled or ingested, and hence to the risk of developing asbestos-related cancer, without the need to demonstrate that fibers from the defendant’s particular product were the ones, or among the ones, that actually produced the malignant growth. *Id.* at 1219 (footnote omitted).

The burden now established, the court turned to the standard jury instructions, BAJI 3.76 and 3.77, and found them “insufficient for [the] purpose” of ensuring that jurors know the “precise contours” of this newly- crafted burden. *See id.* Specifically, the court found that BAJI 3.76 and 3.77

say nothing, however, to inform the jury that, in asbestos-related cancer cases, a particular asbestos-containing product is deemed to be a substantial factor in bringing about the injury if its contribution to the plaintiff or decedent’s risk or probability of developing cancer was substantial.

Without such guidance, a juror might well conclude

that the plaintiff needed to prove that fibers from the defendant’s product were a substantial factor actually contributing to the development of the plaintiff’s or decedent’s cancer. In many cases, such a burden will be medically impossible to sustain, even with the greatest possible effort by the plaintiff, because of irreducible uncertainty regarding the cellular formation of an asbestos-related cancer.

Id. at 1219-20.

To rectify these shortcomings, the court held that in addition to BAJI 3.76 and 3.77, the jury must also be instructed that

the plaintiff need not prove that fibers from the defendant’s product were the ones, or among the ones, that actually began the process of malignant cellular growth. *Instead, the plaintiff may meet the burden of proving that exposure to defendant’s product was a substantial factor causing the illness by showing that in reasonable medical probability it was a substantial factor contributing to the plaintiff’s or decedent’s risk of developing cancer.*

Id. at 1223 (emphasis added). It is this passage upon which the Kennedy requests for a *Rutherford* instruction were based.

Because we conclude that the failure to give a *Rutherford* instruction was harmless error on these facts, it is not necessary for us to decide whether there is an obligation to give such an instruction in cases involving exposure to substances other than asbestos.

B. Harmless Error Analysis

[6][7] Harmless error review applies to jury instructions in civil cases. *See, e.g., Caballero v. City of Concord*, 956 F.2d 204, 206 (9th Cir.1992) (“An error in instructing the jury in a civil case requires reversal unless the error is more probably than not harmless.”). This review is “less stringent” than review for harmless error in a criminal case, but “more stringent” than review for sufficiency of the evidence. *Id.* at 207; *City of Long Beach*, 46 F.3d at 933 (citing *Caballero*). In harmless error review, unlike sufficiency of the evidence review, the “prevailing party is *not* entitled to have disputed factual issues resolved in his favor because the jury’s verdict may have resulted from a misapprehension of law rather than from factual determinations in favor of the prevailing party.” *Caballero*, 956 F.2d at 207 (emphasis added).

[8][9] After careful consideration, we overturn our prior determination and hold that the district court's failure to give a proper *Rutherford* instruction was harmless error. "[A]n error in a trial court's jury instructions relating to the parties' respective burdens of proof ordinarily [requires] reversal." *Larez v. Halcomb*, 16 F.3d 1513, 1518 (9th Cir.1994). *But see Mockler v. Multnomah County*, 140 F.3d 808, 812-14 (9th Cir.1998) (improper instruction on plaintiff's burden of proof held harmless when evidence supported verdict for plaintiff in any event).

*6 In order to sustain their burden of proof, Kennedy needed to prove by a preponderance of the evidence that the radiation from SONGS was a "substantial factor" in causing Mrs. Kennedy's CML. In *Rutherford*, the California Supreme Court cautioned that "[u]ndue emphasis should not be placed on the term 'substantial.'" *Rutherford*, 67 Cal.Rptr.2d 16, 941 P.2d at 1214. As discussed above, this standard minimally requires that the contribution of the individual cause be more than negligible or theoretical. *Id.* at 1219.

[10] Under a preponderance of the evidence standard, the jury is only required to believe that "the existence of a fact is more probable than its nonexistence." *Concrete Pipe and Prods. of Cal., Inc. v. Constr. Laborers Pension Trust for So. Cal.*, 508 U.S. 602, 622, 113 S.Ct. 2264, 124 L.Ed.2d 539 (1993). Therefore, all the jury need have concluded, if given a *Rutherford* instruction, was that it was more probable than not that in reasonable medical likelihood the SONGS radiation was a "substantial factor" in contributing to her risk of developing CML. The SONGS radiation could only have been a "substantial factor" if it played more than an "infinitesimal" or "theoretical" part in bringing about Mrs. Kennedy's CML. On this record, no reasonable juror could have made this finding.

At trial, the defendants introduced uncontroverted expert testimony that, *even if Mrs. Kennedy was exposed to "fuel fleas" as under Kennedy's exposure scenario, there is only a one in 100,000 chance that her CML was caused by the exposure.* [FN5] Indeed the testimony went further--*even assuming that we knew for certain that Mrs. Kennedy's CML was caused by radiation (rather than some other source), there would only be a one in 30,000 chance that "fuel flea" radiation would have been the actual cause.* [FN6] On these facts, the contribution of the "fuel fleas," even assuming exposure and ingestion and with full knowledge that the person in question

actually developed CML, only played "an 'infinitesimal' or 'theoretical' part in bringing about [Mrs. Kennedy's] injury." *Bockrath v. Aldrich Chem. Co.*, 21 Cal.4th 71, 86 Cal.Rptr.2d 846, 980 P.2d 398, 403 (Cal.1999) (quoting *Rutherford*, 67 Cal.Rptr.2d 16, 941 P.2d at 1203). Because no reasonable jury could have found that the "fuel fleas" were a "substantial factor" in causing Mrs. Kennedy's CML, the failure to give a *Rutherford* instruction was harmless error.

II. Products Liability Claims

*7 [11][12] Under California products liability law, a manufacturer may be held strictly liable in tort for placing a defective product on the market if that product *causes* personal injury, provided that the injury resulted from a use of the product that was reasonably foreseeable by the defendants. This doctrine of strict liability extends to products which have design defects, manufacturing defects, or warning defects.

Sparks v. Owens-Illinois, Inc., 32 Cal.App.4th 461, 38 Cal.Rptr.2d 739, 745 (Ct.App.1995) (internal quotation and citation omitted) (emphasis added). Because Kennedy did not meet their burden on causation, we need not address whether California strict liability applies under the Act or whether Mrs. Kennedy was a foreseeable victim. Since Kennedy has not adequately proven causation, their claim fails under both negligence and strict liability regimes.

CONCLUSION

Based on Cal Edison's uncontroverted evidence at trial, no reasonable jury could have found that the "fuel fleas" were a substantial factor in causing Mrs. Kennedy's CML, even under Kennedy's exposure scenario. Therefore, the district court's error in not giving a *Rutherford* instruction was harmless. Further, since causation was not adequately proven, we need not consider the applicability of California strict liability law.

AFFIRMED.

FN1. [CML] results from an acquired (not inherited) injury to the DNA of a stem cell in the [bone] marrow. This injury is not present at birth.... The frequency of the disease increases with age from about one in 1,000,000 children in the first 10 years of life to one in 100,000 people at age 50, to one in 10,000 people at age 80 or above. Disease Information: Chronic Myelogenous Leukemia, The Leukemia & Lymphoma Society, available at

(Cite as: 2001 WL 1131901, *7 (9th Cir.(Cal.)))

[www.leukemialymphoma.org/
all_mat_detail.adp?item_id=2119 & sort_order=4
& cat_id=.](http://www.leukemialymphoma.org/all_mat_detail.adp?item_id=2119 & sort_order=4 & cat_id=)

FN2. A "nuclear incident" includes "any occurrence ... within the United States causing ... [any] sickness, disease, or death ... resulting from the radioactive, toxic, explosive, or other hazardous properties of source, special nuclear, or byproduct material." 42 U.S.C. § 2014(q). It is undisputed that Mrs. Kennedy's death constitutes a "nuclear incident" for purposes of Price-Anderson.

FN3. "Public liability" is defined as "any legal liability arising out of or resulting from a nuclear incident." 42 U.S.C. § 2014(w). A "public liability action" is "any suit asserting public liability." 42 U.S.C. § 2014(hh). It is undisputed that Kennedy's lawsuit is a "public liability action."

FN4. At the underlying trial in *Rutherford*, the plaintiffs had originally requested a burden-shifting instruction based on an alternative liability theory that the California Supreme Court first approved in the celebrated case of *Summers v. Tice*, 33 Cal.2d 80, 199 P.2d 1 (Cal.1948).

FN5. This calculation is known as the Probability of Causation ("PC"). PC is to be distinguished from calculations quantifying increased risk. PC is an ex post calculation, i.e., we know that the individual

has actually contracted the disease. The calculation reflects the odds that the extant disease was caused by the particular exposure in question. The PC that Mrs. Kennedy's CML was caused by her exposure as alleged is one in 100,000. By contrast, the ex ante risk calculation that someone (not yet sick) exposed to "fuel fleas," as Mrs. Kennedy allegedly was, would develop CML attributable to that exposure is less than one in 20,000,000.

It has been urged by distinguished amici in the scientific community that these calculations are themselves based on probabilities so remote as to represent merely theoretical conclusions. The point is not that these numbers are per se unreliable, but that when dealing with the effects of dosages as small as those presented by the "fuel fleas," precision is not currently attainable. Since the calculations present such remote causation data, we advance no view on the issue: whether the PC is actually one in 100,000, one in 92,000, or one in 108,000, makes little difference in this case. There is no argument by Kennedy, and amici do not caution, that the PC calculation is so imprecise as to lead to a deviance that could present a legally viable causation scenario.

FN6. The highest percentage of CML cases any peer-reviewed article in the literature suggests is caused by radiation is five to ten percent. The cause of the remaining ninety to ninety-five percent of CML cases is currently unknown.

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United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 01-1162

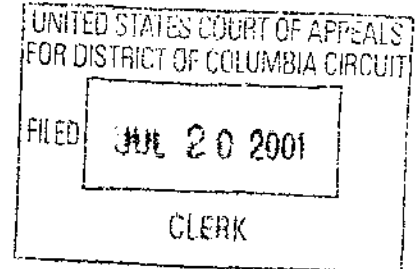
September Term, 2000

Novoste Corporation,
Petitioner

v.

Nuclear Regulatory Commission and United States of
America,
Respondents

Filed On:



ORDER

Upon consideration of petitioner's motion to dismiss petition for review , it is

ORDERED that the motion be granted and this case is hereby dismissed.

The Clerk is directed to transmit forthwith to the respondent a certified copy of this order in lieu of formal mandate.

FOR THE COURT:

Mark J. Langer, Clerk

BY:

Robert A. Bonner
Robert A. Bonner
Deputy Clerk

▲ True copy:

United States Court of Appeals
for the District of Columbia Circuit
By: *[Signature]* Deputy Clerk

UNITED STATES COURT OF FEDERAL CLAIMS

MASSACHUSETTS GENERAL
HOSPITAL,

Plaintiff,

v.

UNITED STATES OF AMERICA,
Defendant.

01 - 434 C

Case No.

FILED JUL 27 2001

COMPLAINT

As and for its Complaint, plaintiff, Massachusetts General Hospital ("MGH"), says as follows.

PARTIES AND JURISDICTION

1. The plaintiff, MGH, was at all times material hereto a charitable corporation pursuant to Massachusetts law, with a principal place of business in Boston, Massachusetts.
2. The late William H. Sweet, M.D. was at all times material hereto on the faculty of the Harvard Medical School and the medical staff at MGH.
3. This action is founded on an indemnity agreement (the "MIT Indemnity Agreement") entered into between the Massachusetts Institute of Technology ("MIT"), and the Atomic Energy Commission (the "AEC"), an agency of defendant United States of America duly authorized by act of Congress to bind the United States, and on a second indemnity agreement believed to exist between Associated Universities, Inc. ("AUI") and the AEC (the "Brookhaven Indemnity Agreement"). Under the MIT Indemnity Agreement and, on information and belief, the Brookhaven Indemnity Agreement, MGH is entitled to indemnity by the United States from certain liabilities, as discussed more fully below. MGH further seeks a declaration that United States is obligated to indemnify them against future claims falling under the Brookhaven and MIT Indemnity Agreements.
4. The Nuclear Regulatory Commission has succeeded to the responsibilities of the AEC under 42 U.S.C. §2210 and under indemnity agreements of the type at issue in this case.

5. This Court has jurisdiction under 28 U.S.C. §1491, in that this action is founded upon an express contract with the United States. This Court has jurisdiction to award declaratory relief under 28 U.S.C. §2201.

FACTS

A. The MIT Indemnity Agreement.

6. In 1958, MIT, a nonprofit educational institution, completed the construction of a research nuclear reactor, known as "MITR-I." The reactor is powered by uranium enriched in the isotope 235. It was constructed with facilities – including an operating room – designed to facilitate its use in medical research and treatment.

7. Under the Atomic Energy Act of 1954, as periodically amended and now codified, in part, at 42 U.S.C. §2210, the AEC was authorized to enter into indemnity agreements with persons licensed to operate nuclear reactors. Such agreements were to bind the AEC, and through it the United States, to indemnify and hold harmless the licensee and other persons indemnified, as their interests may appear, from "public liability" resulting from "nuclear incidents."

8. On or about June 9, 1958, the AEC issued to MIT license no. R-37 to possess and operate MITR-I. The license has been in place, subject to periodic amendments, continuously from 1958 to the present. Copies of the license, and amendments through 1962, are attached hereto as Exhibit A.

9. On or about May 25, 1959 the AEC issued to MIT an interim indemnity agreement, a true and correct copy of which is attached as Exhibit B. MIT accepted and signed the interim indemnity agreement on or about August 1, 1959. By it, the AEC agreed to indemnify MIT, and other persons indemnified as their interests may appear, from public liability in excess of \$250,000 other persons indemnified as their interests may appear, from public liability in excess of \$250,000 arising from nuclear incidents, to a limit of \$500,000,000, including the reasonable costs of investigating and settling claims and defending suits for damage. The Interim Indemnity Agreement recited that it would be superseded in due course by the execution and issuance of a formal indemnity agreement.

10. Subsequently, the AEC issued and MIT accepted Indemnity Agreement No. E-39 (the MIT Indemnity Agreement), a true and correct copy of which is attached as Exhibit C hereto. By the terms of the MIT Indemnity Agreement:

- a. The Agreement was effective from 12:01 A.M., June 9, 1958 forward, and superseded the interim indemnity agreement. (Art. 1, §5 and Attachment, Item 4)
- b. "The Commission undertakes and agrees to indemnify and hold harmless the licensee and other persons indemnified, as their interests may appear, from public liability." (Art. II, §1)
- c. "Persons indemnified" means the licensee [MIT] and any other person who may be liable for public liability." (Art. I, §4)
- d. "Public liability" means legal liability arising out of or resulting from a nuclear incident," with certain exceptions not here relevant. (Art. I, §5)
- e. "Nuclear incident" means any occurrence or series of occurrences at the location or in the course of transportation causing bodily injury, sickness, disease, death, or loss of or damage to property, or loss of use of property, arising out of or resulting from the radioactive, toxic, explosive, or other hazardous properties of the radioactive material," as well as other occurrences not here relevant. (Art. I, §2(a))
- f. The "location" means the MIT reactor building and the area immediately around it. (Attachment, Item 3)

11. "Persons indemnified," "public liability," and "nuclear incident" are statutory terms taken from the Atomic Energy Act, and more particularly 42 U.S.C. §§2014 and 2210(c). These terms are used in the MIT Indemnity Agreement consistently with their statutory meanings, and with the purpose and intent of the Atomic Energy Act.

12. On information and belief, MIT has maintained private liability insurance relative to its operation of MITR-I in an amount of at least \$250,000, continuously since operations began in 1958 to the present.

B. The Brookhaven Indemnity Agreement.

13. AUI, a nonprofit educational and research institution, operated Brookhaven National Laboratory ("BNL") in Upton, New York from 1947 until 1998. Among the facilities at BNL are the AEC-licensed Brookhaven Graphite Research Reactor, which went into operation in 1950, and two other AEC-licensed reactors. On information and belief, each of these reactors was, like MITR-I, the subject of an indemnity agreement (collectively, the "Brookhaven

Indemnity Agreement”) between the AEC and AUI, whose terms were substantially similar to those of the MIT Indemnity Agreement.

C. The Heinrich Civil Action.

14. On or about September 21, 1995, MGH was named as a defendant in a complaint filed in the United States District Court for the Eastern District of New York. Subsequently, the action was transferred to the District of Massachusetts. The Heinrich Civil Action is pending in the United States Court of Appeals for the First Circuit, Docket Numbers 00-2553, 00-2554, and 00-2555. The Complaint has been amended several times since the action was filed. A true and correct copy of the Second Amended Complaint is attached as Exhibit D hereto.

15. The Second Amended Complaint in the Heinrich Civil Action, purports to state claims against which, under the MIT Indemnity Agreement and the Brookhaven Indemnity Agreement, the United States is obligated to indemnify MGH. The Second Amended Complaint claims that MGH is vicariously liable for the conduct of Dr. Sweet, and that MGH is liable for conduct which occurred at BNL under the theory of civil conspiracy. (Ex. D, ¶24). More particularly, the Complaint alleges:

- a. That on June 14, 1951 Joseph Mayne, underwent boron neutron capture therapy (“BNCT”) at BNL. BNCT was a treatment for brain cancer that involved intravenous injection of a boron compound, followed by exposure to neutron radiation at a reactor. (Second Amended Complaint, ¶3, 14)
- b. That on March 6, 1957 a patient named Walter Carmen Van Dyke underwent BNCT in “an operating nuclear reactor” at BNL. (Id., ¶16)
- c. That on January 18, 1961 BNCT was administered to a patient named George Heinrich at the MITR-I reactor. (Id., ¶9)
- d. That on November 13, 1960 a patient named Eileen Sienkewicz received BNCT at MITR-I. (Id., ¶11)

16. The Second Amended Complaint further alleges that the administration of BNCT to the plaintiffs’ decedents caused those decedents radiation-related injury and death, and that Dr. Sweet, MGH and others are liable to their estates and their survivors under a variety of legal theories.

17. The Mayne and Van Dyke claims were dismissed just prior to trial. The Heinrich and Sienkewicz claims were tried in September-October, 1999, and resulted in jury verdicts against Dr. Sweet and MGH for negligence, wrongful death, and punitive damages for wrongful death, as follows:

<u>Plaintiff</u>	<u>Count</u>	<u>Sweet</u>	<u>MGH</u>
Heinrich	Negligence	\$250,000	\$250,000 (joint and several)
	Wrongful Death	\$250,000	\$250,000 (joint and several)
	Death Punitives	\$750,000	\$1,250,000
Sienkewicz	Negligence	\$500,000	\$500,000 (joint and several)
	Wrongful Death	\$2,000,000	\$2,000,000 (joint and several)
	Death Punitives	\$1,000,000	\$2,000,000
TOTALS		\$4,750,000	\$6,250,000

The trial court granted Dr. Sweet/MGH's motion to reduce the jury award. This ruling reduced the compensatory and punitive damages for wrongful death to \$20,000 per plaintiff per defendant. The remaining portions of the judgment remained intact. MGH and Dr. Sweet have appealed the judgment to the United States Court of Appeals for the First Circuit.

D. The Joseph Civil Action.

18. On or about May 23, 2000, Edward A. Joseph, individually and on behalf of the Estate of his father, Nassef Joseph, filed a Complaint in the United States District Court for the District of Massachusetts as *Edward A. Joseph, et al v. Massachusetts General Hospital, Civil Action No. 00-CV-11026-WGY* (hereinafter the "Joseph Civil Action"), raising similar allegations against MGH to those set forth in the Heinrich Civil Action. A true and correct copy of the Joseph Complaint is attached hereto as Exhibit E. More particularly, the Complaint alleges:

- a. That on April 16, 1961, a patient named Nassef Joseph received BNCT at MITR-I. (Joseph Complaint, ¶10).

25. The United States is liable, under the MIT Indemnity Agreement, to indemnify MGH against its costs in defending the Heinrich, Sienkewicz and Joseph claims, and against any liability it may have on those claims upon the entry of judgment.

26. The United States' failure to indemnify MGH under the MIT Indemnity Agreement has caused and continues to cause it great damage.

COUNT II: CONTRACTUAL INDEMNITY; BROOKHAVEN INDEMNITY
AGREEMENT

27. MGH hereby repeats and re-alleges the matters set forth in paragraphs 1 through 26, inclusive, as if fully set forth herein.

28. The United States is liable, under the Brookhaven Indemnity Agreement, to indemnify MGH against its costs in defending the Mayne and Van Dyke claims, and against any liability it may have on those claims upon the entry of judgment.

29. The United States' failure to indemnify MGH under the Brookhaven Indemnity Agreement has caused and continues to cause it great damage.

COUNT III: DECLARATORY JUDGMENT

30. MGH hereby repeats and re-alleges the matters set forth in paragraphs 1 through 29, inclusive, as if fully set forth herein.

31. The Complaints in the Heinrich and Joseph Civil Actions allege that patients Mayne, Van Dyke, Heinrich, Sienkewicz, and Joseph were part of larger series of clinical trials of BNCT using the Brookhaven and MIT reactors, and involving "at least 66 patients." (Second Amended Complaint, ¶2) They have sought, and been denied, class action status, and permission to "notify" putative class members' of the pendency of the action. There is a possibility that other plaintiffs, some or all of whose claims may be subject to the indemnity obligations under the Brookhaven Indemnity Agreement, the MIT Indemnity Agreement, and possible other indemnity agreements, may join in the future or may commence separate actions against MGH.

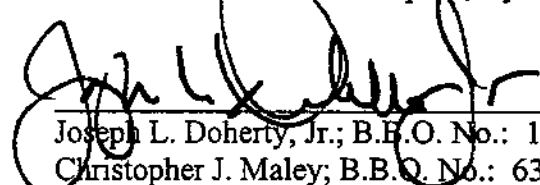
32. An actual controversy has arisen between MGH and the United States as to the United States' obligations to indemnify MGH against defense costs and potential liability in the case of claims brought by or on behalf of patients and/or their families.

WHEREFORE, MGH prays that this Court enter judgment:

- A. Awarding them as damages the amount of their defense costs in the Heinrich Civil Action, in an amount not less than \$669,667.93;

- B. Awarding them as damages the amount of their defense costs in the Joseph Civil Action, in an amount not less than approximately \$9,500.00;
- C. Awarding them as damages any amount for which they may be, or may become, liable in the Heinrich Civil Action;
- D. Awarding them as damages any amount for which they may be, or may become liable in the Joseph Civil Action;
- E. Declaring the rights and liabilities of the parties under the Brookhaven and MIT Indemnity Agreements, and more particularly, declaring that the United States is obligated to indemnify MGH against their defense costs and any potential liability in the case (at least) of any claim brought by or on behalf of any patient who received BNCT at Brookhaven or MIT, and/or their families; and
- F. Awarding MGH such other and further relief as is lawful and proper.

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